

## REMARKS

Claims 1-16 are pending and stand rejected. Applicants respectfully request reconsideration of the present application in view of the amendments set forth above and the remarks below.

### Amendments to the Claims

Applicants amend independent claim 1 to recite a surgical ablation instrument having first and second members *pivottally* coupled to one another and having *non-destructive*, tissue-contacting conductive elements in communication with a source of ablative energy. Support for this amendment can be found throughout the specification and in the drawings, for example on page 7, line 21 to page 8, line 3, and on page 9, lines 22-25. Claim 1 is also amended to include the limitations previously presented in claim 5, which is now cancelled. In particular, claim 1 recites that the second member includes a *distal tissue-piercing tip* formed thereon which is adapted to be deployed into tissue to allow the first conductive element to be positioned on a first tissue surface and the second conductive element to be positioned on a second tissue surface opposed to the first tissue surface such that ablative energy can be transmitted between the first and second conductive elements.

Applicants also amend independent claim 13 to clarify the claim language and to include limitations previously presented in dependent claim 14, which is now cancelled, and to include some of the limitations which have been deleted from claim 15. In particular, claim 13 recites that the first and second members are *pivottally* movable relative to one another, and that the second member includes a *distal tissue-piercing tip* that is adapted to be selectively deployed into tissue. Claim 13 is also amended to recite that the first and second members include a *non-destructive* tissue-contacting conductive surface. As indicated above with respect to claim 1, support for this amendment can be found throughout the specification, for example, at page 9, lines 22-25. No new matter is added.

**Rejections Pursuant to 35 U.S.C. §112**

The Examiner rejects claims 13-16 pursuant to 35 U.S.C. §112 as being indefinite because “the tissue-contacting conductive surface” lacks antecedent basis. Applicants respectfully refer the Examiner to lines 2-3 of claim 13 which recites “...at least a portion of each conductive member having a non-destructive, tissue-contacting conductive surface.” Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

**Rejections Pursuant to 35 U.S.C. §102**

**Bissinger et al.**

Pending claims 1-4, 8, 10, 13 and 15 stand rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,001,096 of Bissinger et al. (Bissinger). The Examiner argues that Bissinger discloses a surgical ablation instrument having first and second members with first and second conductive elements thereon that are adapted to be placed adjacent to tissue to transmit ablative energy therebetween. Applicants respectfully disagree.

Amended claims 1 and 13 recite a surgical ablation instrument having first and second members with *non-destructive*, tissue-contacting conductive elements (claim 1) or surfaces (claim 13). Bissinger does not teach or even suggest such an instrument. As shown in Figure 2A, Bissinger discloses an instrument for endoscopic surgery that includes a handle portion having a tube 18 extending therefrom and containing two insulated wires 32. Each wire 32 includes a spreadable branch 30 formed on a distal end thereof, and each branch 30 includes a bendable section 48 and a cutting blade 52 extending therefrom and having cutting edges 54 formed thereon. In use, when the handle is actuated, “the cutting blades 56 are pivoted relative to one another in a scissor-like fashion, wherein the cutting edges 54 cross each other.” (Col. 3, lines 64-66.) As a result, the instrument is effective to “mechanically cut as well as coagulate, in a bipolar manner, biological tissue . . .” (Col. 4, lines 26-27.) Accordingly, since the cutting blades 52 disclosed by Bissinger are only effective to cut tissue, Bissinger does not teach or even suggest first and second members having *non-destructive*, tissue-contacting conductive elements

or surfaces, as required by claims 1 and 13 of the present invention. Claims 1 and 13 therefore distinguish over Bissinger and represent allowable subject matter. Claims 2-4, 6-12, 14, and 16 are at least allowable because they depend from an allowable base claim.

*Yamauchi et al.*

The Examiner also rejects claims 1-3, 7, 11, 13, and 16 pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,273,887 of Yamauchi et al. (Yamauchi), arguing that Yamauchi discloses a surgical ablation instrument substantially as claimed. Applicants respectfully disagree.

Amended claims 1 and 13 each require that the second member include a *distal, tissue-piercing tip* that is adapted to be deployed into tissue to allow the first and second conductive elements to be positioned on opposed sides of tissue. Yamauchi does not teach or even suggest an ablation device having a *distal, tissue-piercing tip*. Rather, Yamauchi discloses a high frequency treatment tool for coagulating and incising tissue. The device includes opposed tissue gripping members formed on a distal end thereof and, as shown in the drawings, each tissue gripping member has a blunt, rounded, or otherwise non-piercing tip. There is no mention in Yamauchi that the gripping portions can be used penetrate tissue. To the contrary, in each disclosed embodiment, Yamauchi requires the tissue to be positioned between the members, and the members to be closed around the tissue to grip the tissue. Accordingly, Yamauchi fails to tissue or even suggest the claimed invention, and therefore claims 1 and 13 distinguish over Yamauchi and represent allowable subject matter. Claims 2-3, 7, 11, and 16 are at least allowable because they depend from an allowable base claim.

*Cox et al.*

The Examiner also rejects claims 1, 2, and 9 pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,161,543 of Cox et al. (Cox), arguing that Cox discloses a surgical ablation instrument having first and second members movable relative to one another to allow the members to be positioned on opposed sides of tissue for transmitting ablative energy therebetween. Applicants respectfully disagree.

Amended claim 1 recites an ablation instrument having first and second members that are *pivottally* coupled to one another. Cox, on the other hand, teaches various embodiments of an ablation device having first and second probes that are separate and distinct elongate members. In one embodiment, the first and second probes are *slidably* coupled to one another, however the probes do not *pivot* relative to one another, as required by the claimed invention. Amended claim 1 also requires a *distal, tissue-piercing tip* formed on the second member that is adapted to penetrate tissue to allow the first and second members to be positioned on opposed sides of tissue. Cox does not teach or suggest any type of tissue-piercing tip, but rather the probes each have a rounded tip. In fact, since the probes are adapted for use in a minimally-invasive procedure, any type of distal, tissue-piercing tip may cause undesirable damage to tissue as the probes are being guided toward the ablation site. Accordingly, independent claim 1 distinguishes over Cox and therefore represents allowable subject matter. Claims 2 and 9 are at least allowable because they depend from an allowable base claim.

Tetzlaff et al.

Pending claims 1-3, and 12 also stand rejected pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,277,117 of Tetzlaff et al. (Tetzlaff), which the Examiner relies on to disclose a surgical ablation instrument having first and second members that are movable relative to one another, and that includes conductive elements formed thereon for transmitting ablative energy to tissue disposed therebetween. Again, Applicants respectfully disagree.

As indicated above with respect to Yamauchi and Cox, amended claim 1 requires that the second member include a *distal, tissue-piercing tip*. Tetzlaff does not teach or even suggest such a tip, but rather Tetzlaff discloses mechanical forceps having opposed jaws with blunt tips formed on the distal end thereof, as shown in Figure 1. Moreover, the forceps are configured to grip or clamp tissue, e.g., a blood vessel, during an open surgical procedure, and therefore the use of any type of piercing tip would not be desirable as it may cause damage to adjacent tissue. Amended claim 1 therefore distinguishes over Tetzlaff and represents allowable subject matter. Claims 2-3, and 12 are at least allowable because they depend from an allowable base claim.

**Rejections Pursuant to 35 U.S.C. §103**

The Examiner rejects dependent claim 6 pursuant to 35 U.S.C. §103(a) as being unpatentable over Yamauchi. As noted above, claim 1 distinguishes over Yamauchi, and thus claim 6 is allowable at least because it depends from an allowable base claim. Applicants respectfully request reconsideration and withdrawal of this rejection.

**Conclusion**

In view of the amendments and remarks above, Applicants submit that claims 1-4, 6-13, and 15-16 are in condition for allowance and allowance thereof is respectfully requested. Applicants encourage the Examiner to telephone the undersigned in the event that such communication might expedite prosecution of this matter.

Respectfully submitted,

Date: April 23, 2004

  
Lisa J. Michaud, Reg. No. 44,238  
Attorney for Applicants

NUTTER, McCLENNEN & FISH, LLP  
World Trade Center West  
155 Seaport Boulevard  
Boston, MA 02210  
Tel: (617)439-2550  
Fax: (617)310-9550

1320668.1